

**REMARKS**

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

**Status of the claims**

Claims 17,18, 21-27, 29-49 were pending in the subject application, of which claims 32-48 had been withdrawn from consideration by the Examiner. With this submission, claims 17, 23, 24, 29 and 49 have been amended. Further, claim 30 has been canceled, and claim 50 has been newly added. Upon entry of this paper, therefore claims 17, 18, 21-27, 29, 31-50 will remain pending, with claims 17, 18, 21-27, 29, 31, 49 and 50 remaining under active consideration.

**Statement of the substance of an Interview**

Undersigned counsel wishes to thank Examiners Greene and Eyler for extending the courtesy of an Interview held at the USPTO on 08 July 2010. As noted in the Interview Summary of even date, the “obviousness” rejections were discussed in view of the cited references. Counsel explained that the present inventors had discovered that protein from demineralized milk could be provided at concentrations heretofore impossible with nutritional compositions and yet maintain a viscosity “below 50 mPa.s at a shear rate of 100 s<sup>-1</sup> and a temperature of 20° C.” The Examiners suggested that Applicant recite the “viscosity” proviso in the claims and remark on the relationship between protein source, content, and viscosity. Applicant has endeavored to do so.

**35 U.S.C. § 103 rejections**

Claims 17, 18, 21-27, 39-31 and 49 stand rejected under 35 U.S.C. § 103 as being allegedly unpatentable over US 2002/0142025 (“Hageman”) and US 6,605,310 (“Fuchs”) in view of US 5,576,303 (“Shibuya”) and US 4,146,456 (“Taneya”). The Examiner appreciates that Hageman does not teach a composition comprising “8.5 – 12 g intact protein per 100 ml”. Indeed, the only arguable reference to “intact” protein may be found in Example 4 of Hageman, which provides a composition comprising 8.2 g protein (casein/whey 80/20) per 100 ml. For this reason, the Examiner has introduced Fuchs for “teach[ing] a higher protein

content liquid oral supplement and provid[ing] motivation to increase the protein content of a liquid oral supplement.” Action, p. 5. On this point, it is noted that Table 1 teaches a composition comprising 9g protein (caseinate/soy) per 100 ml.

Applicant does not dispute that the artisan had “desired to provide nutritional supplements having increased energy as well as increased protein per serving.” Fuchs, col. 1, ll. 47-49. Rather, Applicant stresses that a concomitant increase in viscosity has heretofore limited the level of intact protein able to be supplied in consumable liquid compositions. As Fuchs explains, “increasing both calories and/or protein in a nutritional supplement can increase the overall viscosity of the supplement. This can make the supplement difficult to consume or administer... .” *Id.* at col. 1, ll. 56-60. In fact, higher concentrations of proteins lead to “precipitation, coagulation, non-emulsifying properties, creaming, gelling or high viscosity” either during shelf life or during processing, especially heat treatment. Specification, p. 2, para. 4.

The present inventors, however, discovered that protein obtained from demineralized milk<sup>1</sup> allows high concentrations of protein without the art-recognized viscosity problems. *Nothing in the art presaged this discovery*, predicated on which, the applicant was the first to achieve a liquid composition comprising 8.5 -12 g of intact protein per 100 ml, yet having “a viscosity below 50 mPa.s at a shear rate of 100 s<sup>-1</sup> and a temperature of 20° C.”<sup>2</sup> In other words, even assuming a general motivation to increase protein concentrations as alleged by the Examiner, the artisan simply could not have fathomed a reasonable expectation of concomitantly *reducing* viscosity of the resulting composition. M.P.E.P. § 2143(II) (noting that “[o]bviusness does not require absolute predictability, however, at least some degree of predictability is required.)

Fuchs is instructive of the state of the art at the time the present invention was made. Fuchs teaches that the protein fraction “can” consist entirely of caseinate. However, “[b]ecause caseinate may increase the viscosity of the supplement, a *blend* of caseinate and soy protein isolate may be desired.” Col. 3, ll. 34-49 (emphasis added). So, Fuchs suggests

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<sup>1</sup> By way of background, demineralization removes substantially all lactose from milk, leaving essentially intact protein; the protein is enriched in calcium relative to sodium, potassium and other electrolytes. Specification, p. 4, para. 5.

<sup>2</sup> The claims have been amended to incorporate this limitation.

blending caseinate with soy protein isolate in a ratio of approximately 75:25 to approximately 50:50, respectively. *Id.* A “70:30” blend has a viscosity of approximately 95 cP and a “60:40” blend—as found in the compositions of Table 1—has a viscosity of approximately 85 cP. *Id.*

As will be next explained, by using demineralized milk as the protein source, the claimed compositions are able to reduce viscosity by at least 35 cP when compared to a Fuchs composition comprising an equivalent amount of casein (*i.e.*, 60%).

The claims require that at least 70 wt.% of the intact protein fraction is obtained by demineralizing milk. Milk contains only two types of proteins, casein and whey protein, in a relatively fixed weight ratio of about 80:20, respectively.<sup>3</sup> Hence, at least 80% of the 70% ( $0.80 \times 76\% = 56\%$ ) of the intact protein in the claimed compositions will be casein. At this concentration of casein (*i.e.*, 60%), Fuchs observes a viscosity of at least 35 cP higher than the viscosity range recited for the claimed composition. Again, nothing in the art would have led the artisan to reasonably expect such a result.

Indeed, the concentration of protein is the most significant variable in a nutritional composition affecting its viscosity. For this reason, of the myriad of ingredients discussed by Fuchs (carbohydrates, lipids, etc.), only protein—casein, in particular—is discussed in the context of viscosity. Col. 3. For at least these reasons, Applicant respectfully submits that the present claims cannot be rendered obvious in view of the references cited. Withdrawal of the subject rejections are accordingly solicited.

## Conclusion

Applicant believes that the present application is in condition for allowance. Favorable consideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment,

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<sup>3</sup> See, *e.g.*, Lara-Villoslada, F, J. Dairy Sci. 88:1654, 2d col, 2d para. (attached to IDS being filed concurrently herewith) .

to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing or a credit card payment form being unsigned, providing incorrect information resulting in a rejected credit card transaction, or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. § 1.136 and authorizes payment of any such extension fees to Deposit Account No. 19-0741.

Respectfully submitted,



By \_\_\_\_\_

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FOLEY & LARDNER LLP

Customer Number: 22428

Telephone: (202) 295-4621

Facsimile: (202) 672-5399

Gilberto M. Villacorta, Ph.D.

Registration No. 34,038

Sunit Talapatra, Ph.D.

Registration No. 54,482